

Award Number: **W81XWH-11-2-0129**

TITLE: PHIT for Duty, a Personal Health Intervention Tool for Psychological Health and Traumatic Brain Injury

PRINCIPAL INVESTIGATOR: **Paul N. Kizakevich, M.S., P.E.**

CONTRACTING ORGANIZATION: **RTI International**
Research Triangle Park North Carolina 27709

REPORT DATE: **June 2016**

TYPE OF REPORT: **Final**

PREPARED FOR: **U.S. Army Medical Research and Materiel Command**
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

■ Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE June 2016		2. REPORT TYPE FINAL		3. DATES COVERED 15 Mar 2011 - 14 Mar 2016	
4. TITLE AND SUBTITLE PHIT for Duty, a Personal Health Intervention Tool for Psychological Health and Traumatic Brain Injury				5a. CONTRACT NUMBER W81XWH-11-2-0129	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Paul N. Kizakevich E-Mail: kiz@rti.org				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709-2194				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The purpose of this project is to help prevent psychological disorders in high-risk individuals with early symptoms of stress, depression, substance use, and other health problems. PHIT for Duty integrates self-report and physiological sensor instruments to assess health status via screening questionnaires for stress, anxiety, sleep quality, depression, and alcohol use. An expert system, called the intelligent virtual advisor (IVA), processes these data using evidence-based logic to determine health risk and to prescribe SHIs including mindfulness meditation, health education, and cognitive behavior change modules for reducing stress, attentional restructuring, improving sleep and reducing alcohol use. Persons with high risk are advised to consult their primary care provider for a professional health assessment. Persons with mild or moderate risk (i.e., subclinical scores), are presented with a suite of interventional, therapeutic, and monitoring activities to support post-traumatic stress reduction. These include skills acquisitions (e.g., mindfulness meditation), health education (e.g., sleep hygiene), cognitive behavior change (e.g., alcohol use), and self-monitoring activities. The mindfulness content comprises learning materials and meditation practices, and is provided both as a six-week structured course and as self-administered resources. A "to-do" list of assessments and activities is updated daily and displayed on the PHIT for Duty home screen as a menu for the user. Usability evaluation of the PHIT for Duty health assessments, physiological sensors, system acceptability, and overall system functionality have shown positive results and affirmation of the PHIT mobile application framework design..					
15. SUBJECT TERMS PTSD, post-traumatic stress disorder, mobile health, self-help, iOS, Android, mindfulness, relaxation training, sleep, alcohol					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	23	19b. TELEPHONE NUMBER (include area code)

Table of Contents

Section	Page
1. INTRODUCTION	4
2. Keywords	4
3. Overall Project Summary	4
3.1. <i>Concept formation and development planning</i>	<i>5</i>
3.1.1. Focus Groups.....	5
3.1.2. Findings.....	5
3.1.3. Recommendations	7
3.2. <i>App development and evaluation.....</i>	<i>8</i>
3.2.1. Personal Health Information Toolkit.....	8
3.2.2. PHIT for Duty research app	11
3.2.3. Usability and beta testing	14
3.3. <i>Preparing for distribution.....</i>	<i>15</i>
4. KEY RESEARCH ACCOMPLISHMENTS	19
5. REPORTABLE OUTCOMES	20
5.1. <i>Manuscripts, abstracts, presentations</i>	<i>20</i>
5.2. <i>Licenses applied for and/or issued</i>	<i>21</i>
5.3. <i>Degrees obtained that are supported by this award</i>	<i>21</i>
5.4. <i>Development of cell lines, tissue or serum repositories</i>	<i>21</i>
5.5. <i>Infomatics such as databases and animal models</i>	<i>21</i>
5.6. <i>Funding applied for based on work supported by this award</i>	<i>22</i>
6. CONCLUSIONS	23
7. REFERENCES	23

1. INTRODUCTION

The goal of this project is to support prevention of psychological health problems and post-traumatic stress disorder (PTSD) through innovation in mobile personal health assessment and self-help intervention (SHI).

To address this goal, we developed and evaluated PHIT for Duty, a field-deployable mobile application (app) to help build resilience in healthy troops and support prevention in high-risk personnel. Based on RTI's Personal Health Intervention Toolkit (PHIT), PHIT for Duty integrates health assessments with an intelligent virtual advisor (iVA) that recommends, tailors, and presents self-help advisories based on established rules and processes. PHIT for Duty was initially implemented as a research platform integrating a mobile app with nonintrusive physiological sensors for health status monitoring and multiple SHI resources.

PHIT for Duty is intended to be used for secondary prevention of psychological health problems in persons who have been exposed to psychological trauma and may be having some symptoms of distress, but have not been diagnosed with any psychological disease or disorder. PHIT for Duty, however, may eventually prove useful as a treatment option, and therefore was developed with strong beta testing and quality assurance software development practices.

2. Keywords

Post-traumatic stress disorder, PTSD, mobile health, apps, relaxation training, sleep, alcohol

3. Overall Project Summary

As originally envisioned, the project comprised five tasks (1) formative research to identify psychological assessments and SHIs to assist individuals in dealing with combat and operational stress and the psychological and physiological consequences of that exposure; (2) development of personal, mobile technologies for longitudinal health assessment and SHI; (3) testing, refinement, and validation of PHIT for Duty technologies through beta testing; (4) evaluation the efficacy of the PHIT methodology for prevention in a pilot study and subsequent randomized controlled trial (RCT) with post-deployed personnel; and (5) adapting the developed system for several popular smartphone or tablet computer platforms, including both Google Android™ and Apple iOS based devices. Recruiting for the pilot study was very disappointing and resulted in merely two participants. Consequently both the pilot study and RCT were canceled. This report is therefore limited to presenting the activities and results for each of the more salient and principal components of the PHIT for Duty research and development project.

3.1. Concept formation and development planning

At the outset, formative research was conducted to help establish the vision, requirements, and approach for PHIT for Duty development and evaluation through a series of interactions with scientific and clinical advisors, military leaders, prospective users, and other stakeholders. Our objective was to identify psychological health problems that might be mitigated via the PHIT for Duty app, self-help interventions to incorporate in the device, operational issues regarding use post deployment, and identify the needs of PHIT end users and stakeholders prior to PHIT for Duty app development.

3.1.1. Focus Groups

Three 90-minute focus groups were conducted with soldiers from the Warrior Transition Battalion (WTB) at Ft. Bragg. Focus groups were conducted in a private conference room housed at the WTB headquarters. Informed consent was obtained at the start of each focus group session. A trained focus group moderator led each discussion and each session was audio recorded.

There were a total of 14 participants across three groups, all male, having a range of one to six deployments. All had returned from deployment within the last twelve months. The research team took measures to ensure that the participants felt emotionally and physically comfortable sharing experiences. One participant shared that he needed to sit in “his safe space” which was across from the door and with his back to the wall. He also requested that the group not make eye contact with him as it would make him feel uncomfortable and he might “flip out.” The moderator was sensitive to the vulnerability of these participants and would redirect conversations that were becoming emotionally charged.

The questions asked during each session focused on key areas that would help the research team identify psychological health problems, self-help interventions (SHIs), operational issues, and deployment concerns. Additional topics discussed include post-deployment health problems, incentives for study participation, study recruitment strategies, device usage preference (tablet vs. smartphone), acceptability of proposed SHIs such as relaxation exercises, and willingness to use physiological monitoring devices.

3.1.2. Findings

Post deployment health problems. The top three post deployment health problems mentioned were depression, anxiety and sleep issues. Additional problems discussed include stress, aggression, social withdrawal/avoidance, memory issues, substance abuse, nightmares, breathing problems, and pain. Stressors mentioned include financial and relationship issues experienced in post deployment. Participants across all three groups discussed the stigma associated with seeking help for most post deployment health problems mentioned. It is also important to note that soldiers reported that many post deployment health problems do not appear until a few months after return from deployment.

- “I can’t stay asleep and sleep about an hour and then wake up and stay up for maybe two or three hours. This happens night after night.”

-
- “Crowds and traffic are difficult. You are constantly on guard about people coming close to you and vehicles driving near you.”
 - “Nothing really happens the first three months (post deployment) when you are trying to unwind and get back into your life.”

Post deployment support. Participants acknowledged the stigma associated with seeking help for most post deployment health problems. Across all three groups, soldiers reported not being honest when responding to post deployment health assessments (PDHAs). Soldiers responded positively about the provision of post deployment support by way of a personal app. The use of this app would allow for soldiers to seek help privately without calling attention to their difficulties adjusting post deployment, thereby reducing the stigma and risk associated with utilizing behavioral health services. Participants recommended that the study emphasize that the names of soldiers who use the app after deployment will not be shared with the chain of command. The importance of confidentiality was repeatedly mentioned.

- “The Army offers a lot of resources (for post deployment issues) but what happens, I think, is that if a soldier decides to use it he worries too much about the consequences of what people are going to think and it is like taboo and that is what it comes down to.”
- “If you are labeled a soldier with PTSD then you automatically trigger thoughts of them being crazy.”

Incentives. Numerous incentives were discussed during the focus groups. Soldiers reacted positively to the idea of being provided with a portable electronic device for three months. The provision and use of an electronic device would serve as an incentive for many soldiers to encourage participation in the study if the device could also be used for their personal use. Soldiers clarified that their strong preference would be for the provision of a tablet as opposed to a smartphone, as most soldiers already own a smartphone. All soldiers agreed that access to free Wi-Fi, movies, music, and games would be an incentive. The use of new and/or hard to obtain electronic devices would be an additional incentive.

- “Games like Angry Birds would be good.”
- “The appeal would be the model (of electronic device) and if it were hot off the press kind of thing.”

Study recruitment. A major theme that was present in all focus group discussions regarding study recruitment was the importance of stressing confidentiality and the voluntary nature of the study. Soldiers did not want their chain of command to be notified of their study participation and strongly suggested that recruitment efforts not be associated with the Army. Soldiers shared that the study team would need to gain the trust of the soldiers. More specifically, trust that we would not share their data with their chain of command was emphasized. Once trust was established, soldiers would suggest the study to their peers which would aid in recruitment efforts. One participant thought that younger soldiers would be harder to recruit because they think they are “indestructible.” Another suggested recruitment strategy was to hold “briefing” sessions off base (again stressing the separation of the study and the Army). Recruiting via Facebook or radio commercials was also suggested. Contrary to what was previously shared, one soldier recommended that we partner with Military Family Life Consultants (MFLC). MFLC are not allowed to inform the chain of command unless a soldier is threatening to hurt

themselves or others. Barriers to participation included the time commitment and soldiers not wanting to address post-deployment problems for fear of being identified by their chain of command.

- “The Military Family Life Consultants (MFLC) would be good and can’t tell your chain of command and are under the radar.”
- ”Keep everything about what is being put in that system. Keep stressing confidentiality because of the trust issue with soldiers.”

Use of physiological monitoring devices. The majority members were enthusiastic and amenable to using the psychological monitoring devices. Concerns were mentioned about charging the devices. There was significant interest in monitoring sleep behaviors as many soldiers shared having sleep issues. Soldiers were eager to receive feedback on their quality of sleep. One participant suggested the use of a sleep monitor would encourage participation and this could be focused on during recruitment. Feedback from the physiological monitoring devices may serve as an incentive for some participants.

- “I would be willing to that (wear sleep monitor). I would really like to know how I am sleeping.”
- “I personally think it would be fun to see what my heart rate was doing.”

General feedback. Soldiers suggested sending study reminder notifications via text message to their personal phone to ensure compliance with the daily health assessments. The length of the SHIs should be ten minutes or less per day. Soldiers would lose interest after ten minutes. We received mixed feedback on the relaxation exercises. A few participants have practiced relaxation techniques and have found them effective. Soldiers consistently shared that they are interested in receiving feedback on how their health has changed over time. One soldier feels that participants will just tell us “what we want to hear.” The use of the app by family members was suggested numerous times. Soldiers feel that the family/friends could benefit from learning more about how to cope with post-deployment health issues. Soldiers recommended that the app include an easy to find resource list on phone numbers if needed.

- “The app is clean and I like it a lot”.
- ”If you stress that you are building a system to help future soldiers and not say that we are analyzing them (the participant) they won’t feel like they are being judged and are more likely to help (participate).”

3.1.3. Recommendations

After reviewing these findings and observations, we arrived at the following recommendations:

- If possible, PHIT for Duty should be implemented three to six months post-deployment, as this is the timeframe when post-deployment health issues surface.
- The mobile electronic device of preference was the tablet.
- Study recruitment will need to stress confidentiality and not involve the chain of command.
- Soldiers have concerns about confidentiality.
- Soldiers are willing to use physiological monitoring, and feedback could serve as an incentive.

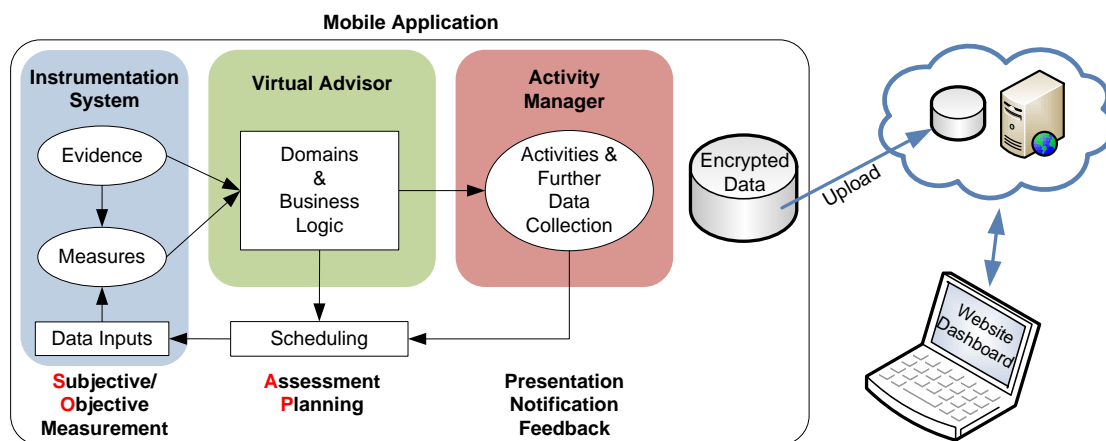
3.2. App development and evaluation

Although the goal of this project was to develop and evaluate a singular app for post-deployment psychological health, we saw the potential for other health research apps that could be based on variations of PHIT for Duty. Therefore we first developed a more generalized methodology for implementing research-oriented apps, the Personal Health Information Toolkit (PHIT) app framework. The PHIT framework eased PHIT for Duty implementation, enabled to production of various test versions and protocol variants, and contributed to development of multiple subsequent health research apps.

3.2.1. Personal Health Information Toolkit

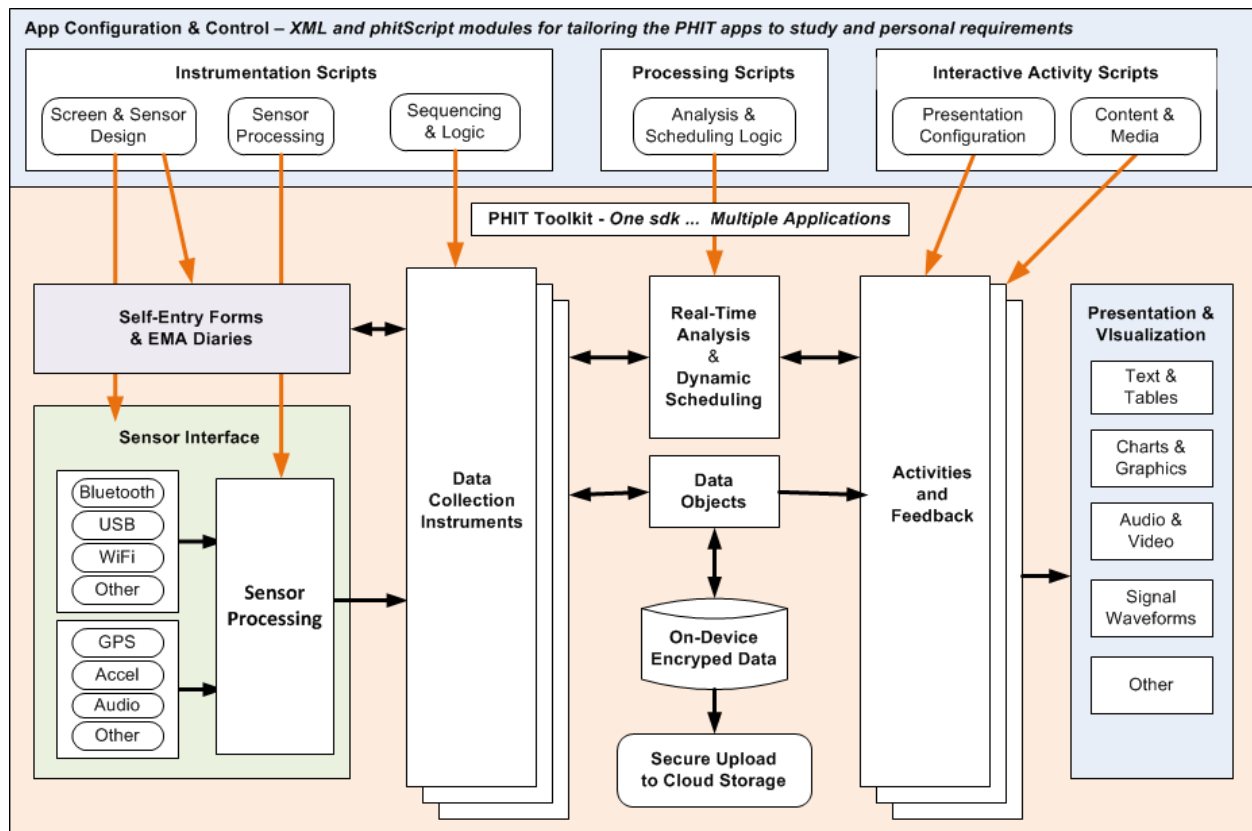
The PHIT framework integrates multimodal data collection with an intelligent virtual advisor (iVA) that analyzes data to recommend, tailor, and present activities based on established rules and scripted processes (**Exhibit 1**). PHIT facilitates building complex smartphone/ tablet applications with both self-entry and autonomous sensor-based instruments. Objective data are acquired via cognitive tests, interactive exercises, serious games, and external sensors. Virtual instruments can be created with no user interface such as retrieving the current GPS location, uploading data, or performing other tasks that do not require direct user interaction. The iVA provides a logic layer where data analysis and planning take place. Additionally, an activity manager allows for dynamic tailoring of knowledge and skills acquisition, assessment feedback, health alerts, and other interactions (Kizakevich et al., 2012; Eckhoff et al., 2015). Apps are self-contained and run offline on the device. Data are stored locally using an encrypted database, and then securely uploaded to a secure server when internet access becomes available.

Exhibit 1. PHIT mobile application framework architecture.



An app built using the PHIT framework comprises two primary implementation components: (1) app-specific configuration and control scripts (in XML) with instrument definition, iVA processing, and activity/intervention scripting along with domain-specific content assets; and (2) the user-facing app itself, with self-entry forms and diaries, research-grade sensor processing, instrument manager, data analysis and task scheduling, activity manager, and visualization (**Exhibit 2**).

Exhibit 2. Personal Health Intervention Toolkit (PHIT) application run-time architecture.



The App Configuration and Control (ACC) module configures PHIT for a particular study, including screen-based self-report information, ecological momentary assessment (EMA) diaries, and sensor data sources and signal processing networks. The configuration scripts are in extended markup language (XML) and use an RTI language called phitScript to construct program logic and activate special functions. The scripts also configure on-device analyses, dynamic task scheduling logic, decision support, and participant health and environmental alert criteria. Finally, the ACC module loads data presentation scripts to construct virtual reports and graphics for user feedback, notification, and visualization of data streams and results.

The sensor interface (SI) handles the plug-and-play configuration for a range of standard interface technologies and executes sensor setup scripts to control sensor functions and initiate data collection. Received sensor data are optionally processed using digital filtering, feature detection (i.e., peaks, valleys), and signal timing and amplitude measurements to derive specific health, environmental, and behavioral measures.

Based on the PHIT architecture (Eckhoff et al., 2015), the core manages the main screen menu, form-by-form presentation of multiform self-entry instruments, scheduling of the instrument to the Home screen task list, data object representation and secure storage, on-device execution of phitScript analysis programs, and generation of a variety of screen and media outputs for user feedback and data

visualization. Self-entry forms and diary screens, analysis, presentation, scheduling, uploading, and participant interactions are implemented via XML using standardized widgets (**Exhibit 3**).

Exhibit 3. Data collection and presentation widget examples.

Data Collection – Multiple methods and formats

Simple

- Text, number entries
- Checkbox, radio button
- Date, time, calendar
- Select buttons, with icons
- Likert scale, slide bar

Complex

- Child-oriented data forms
- Bluetooth sensors
- Smartphone sensors
- Reaction time
- Heart rate variability
- Electronic signature

User Activities – Information, skills acquisition, and feedback

Simple

- Image, video, audio
- Narrated slideshow
- Charts, tables, alerts
- Websites (embedded)
- YouTube (embedded)

Engaging

- Video vignettes
- Games, exercises
- Simulations
- GPS mapping
- Signal graphing
- Virtual reality
- Notification reminders

Using such forms and widgets, a variety of data collection instruments and several health interventions have been developed (**Exhibit 4**). These resources can be easily reused and tailored for to mobile health app requirements using XML-based scripts and configuration settings.

Exhibit 4. Library of health assessment instruments and self-help intervention resources.

Assessment Instruments	Health Interventions
Alcohol Use Disorder Identification Test (AUDIT)	Arousal Control
Brief Anger Assessment (BAA)	Arousal Control (meditation)
Brief Coping Scale (Brief Cope)	Attention Absorption
Brief Traumatic Brain Injury Scale (BTBIS)	Attention Absorption (meditation)
CAGE Questionnaire (CAGE)	Combat & Operational Stress Control
Clinical Anger Scale (CAS)	Mindfulness-Based Stress Relaxation
Combat Exposure Scale (CES)	Relaxation Breathing
Concussion Checklist (CCL)	Mindful Body Scan
Connor-Davidson Resilience Scale (CD-RISC)	Sitting Meditation
Difficulties in Emotion Regulation Scale (DERS)	Walking Meditation
General Anxiety Disorder-7 (GAD-7)	Pain & Somatic Discomfort Mgmt.
Impact of Event Scale-Revised (IES-R)	Alcohol and Stress
Insomnia Severity Index (ISI), with nightmares	Calories, Costs, and Consequences
Multidimensional Scale of Perceived Social Support	Drink Smarter Skills
Perceived Stress Scale-10 (PSS-10)	Blood Alcohol Level Simulator
Pittsburgh Sleep Quality Index (PSQI)	Improving your Sleep
Pittsburgh Sleep Quality Index Addendum (PSQIA)	Preparing for Sleep
Psychological Health Questionnaire (PHQ-8)	Personal and Environmental Factors
PTSD Checklist-Military (PCL-M)	Reclaiming your Bedroom
Short Screening for PTSD	Sleep Smarter Skills
User Demographics and History	Nightmares

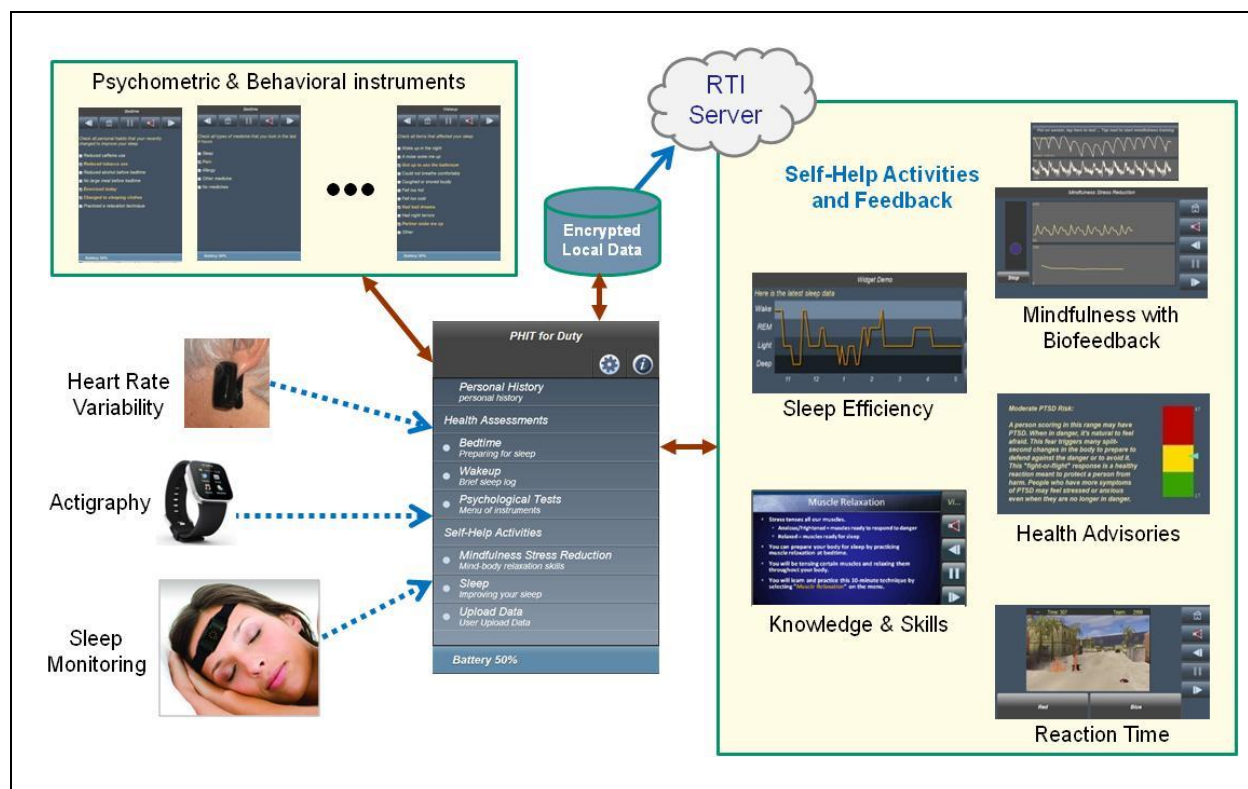
The PHIT framework is extensible, flexible and secure. Developing PHIT app modules, such as instruments, activities, and iVA modules, is straightforward yet the XML structures and scripting provide considerable power in customizing the content. For example, as a health assessment (e.g., for anxiety) is completed, these data are immediately available to the iVA, which is able to determine how to proceed with the user. The iVA may choose to begin a SHI or contact a clinician for referral. User actions, like completing a sleep quality questionnaire, are managed via a user-friendly task menu screen. The task list is updated daily according to logic rules managed via the iVA. Periodic assessments of various domains are analyzed to instruct users and recommend activities tailored to the scope of the application.

All data are be tagged at the time of acquisition with an array of indices to facilitate analysis and ensure data integrity. These include observation ID, date, time, study ID, protocol ID, participant ID, device ID, instrument source ID, and unit of measurement. All acquired raw and derived data are available for local analysis and presentation, encrypted and stored, and uploaded daily to central storage.

3.2.2. PHIT for Duty research app

The PHIT for Duty research application comprises a variety of subjective and objective data collection instruments, interactive self-help activities, health information, personal feedback, and other presentation modules (**Exhibit 5**). Required user actions, like completing a brief morning sleep quality questionnaire, are managed via a task menu screen. The task list is updated each day according to logic rules managed via the intelligent virtual advisor.

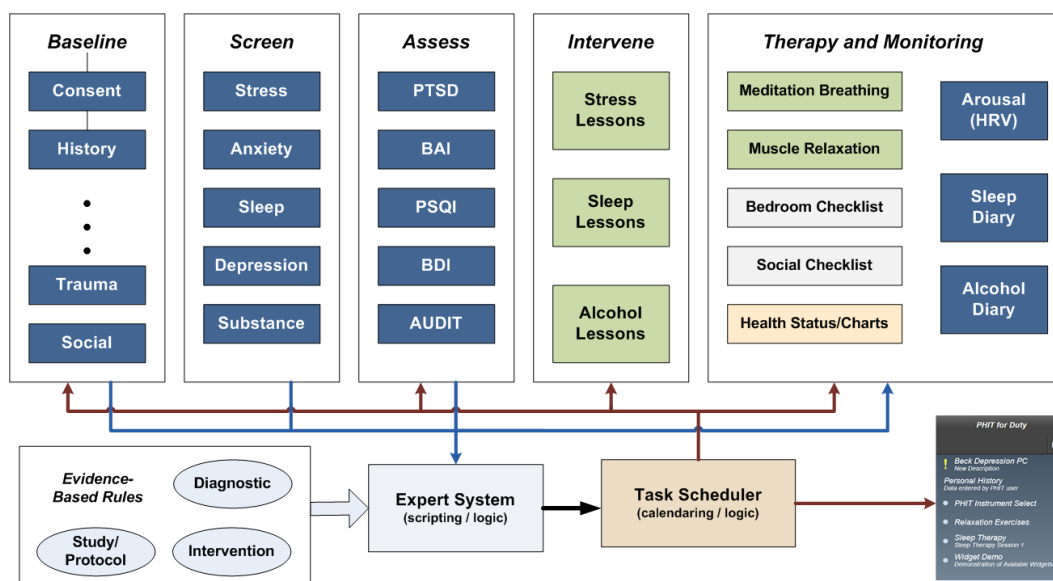
Exhibit 5. Representative data collection instruments, user task menu, self-help activities, and health information feedback modules in the PHIT for Duty application.



At baseline, personal, psychological, social, and combat history data are collected (**Exhibit 6**). Then, on a periodic basis (e.g., bi-weekly), health status is assessed via brief screening questionnaires in five domains (i.e., stress, anxiety, sleep quality, depression, and alcohol use). For each domain, the screening data are analyzed and a subsequent assessment is given should the screener score meet certain criteria. Any such detailed assessment is categorized by none, mild, moderate, or likely risk of disease for that domain.

Persons with likely risk are advised to consult their primary care provider for a professional health assessment. Persons with mild or moderate risk (i.e., subclinical scores), are presented with a suite of interventional, therapeutic, and monitoring activities to support post-traumatic stress reduction. These include health management information (i.e., cognitive lessons), skills acquisitions (e.g., meditation, muscle relaxation), tools (e.g., sleep hygiene checklist), and self-monitoring activities (e.g., alcohol use diary). All of these screening instruments, assessment instruments, and self-help interventional activities, as well as the iVA health management expert system, are components of the PHIT for Duty smartphone/tablet mobile application. The “to-do” list of assessments and activities to be performed by the user is updated daily and displayed on the PHIT for Duty task list.

Exhibit 6. PHIT for Duty health assessment and preventive intervention schema.



For objective measurement of psychological arousal, we developed a system comprising a wireless pulse sensor clipped to the earlobe (**Exhibit 7**) and software to display pulse, heart rate (HR), and heart rate variability (**Exhibit 8**). The pulse sensor (Binar HeartSensor model HRS-08WE, Binar Integrated Mobile Systems, LLC, Poulsbo, WA) is a very small and unobtrusive device with a Bluetooth wireless connection, and can be used to assess cardiac arousal almost anywhere and anytime. We tested the device and have found the ear pulse wave to be free of artifacts and usable up to 4 hours on a battery charge.

The HRV processor receives a continuous pulse waveform at 300 Hz, uses digital filters to clean the waveform, and identifies sequential heart beats in real time. At a set interval (e.g., every 5 seconds), the HR analyzer examines the prior 60 seconds of pulse information and determines average HR, the average interbeat interval (IBI), and multiple measures of HRV. The raw and clean HR waveforms and derived HR and HRV measurements are stored in the PHIT database and plotted on the device (**Exhibit 8**).

Exhibit 7. Bluetooth wireless pulse sensor



Exhibit 8. HR, HRV and pulse waveforms.



3.2.3. Usability and beta testing

Usability was evaluated in a series of at-home studies ranging from 7-14 days in 31 civilian participants conducted throughout 2013 to evaluate functionality and performance, gain user feedback, and yield usability measures of system features (**Exhibit 9**). These studies were designed to engage participants in various aspects of the PHIT for Duty devices, software modules, assessment instruments, and intervention activities. Testing was performed in waves of five participants, allowing time between waves for revising software and procedures based on user feedback (Kizakevich et al, 2014).

Prior to testing, informed consent was acquired, training was given, and a user manual was provided. Participants took their PHIT devices home and performed a series of scheduled activities over a designated time frame. Self-report assessments and diaries were tested using a mix of sham and actual data including daily bedtime and wakeup sleep diary entries, mindfulness-based stress reduction training with heart rate variability biofeedback, simple reaction time testing, and additional health assessments and intervention activities. Some participants also tested the ear pulse sensor (N=23), Zeo sleep monitor (N=27), and wrist actigraphy (N=27). Participants were debriefed on system usability, technical performance, and suggestions for improvements via a common debriefing questionnaire. Summary results for the primary usability components are as follows:

Exhibit 9. Integrated usability test results.

System and Device Usability - Range of 1 to 5 (very hard to very easy)		
<i>PHIT Subsystem</i>	<i>Mean ± SD</i>	<i>N</i>
Overall system	4.5 ± 0.6	31
Self-report instruments	4.5 ± 0.7	31
Ear pulse sensor	3.7 ± 1.2	23
Zeo sleep monitor	4.4 ± 0.7	27
Sleep Monitor Comfort - Range of 1 to 5 (very uncomfortable to very comfortable)		
<i>PHIT Subsystem</i>	<i>Mean ± SD</i>	<i>N</i>
Zeo sleep monitor	3.7 ± 1.1	27
Wrist actigraphy	2.7 ± 0.9	27

The System Usability Scale (SUS) was used to quantify usability of the PHIT for Duty system in last four participants of the 14-day day field test and the five participants of the 28-day simulated pilot test. The average SUS score reported by these nine participants was 85±12 (mean±sd). The percentile rank for this average score is 95%, meaning that the usability of the near-final PHIT for Duty system exceeds 95% of all products tested using the System Usability Scale.

3.3. Preparing for distribution

While the initial PHIT for Duty app served well for research purposes, the emphasis on collecting a array of research measurements made it inappropriate for general use. It was therefore necessary to refactor PHIT for Duty to align the health assessment and self-help intervention components with the expected needs of a broader potential user community. Most of the health, social, behavioral, and combat experience assessments were removed, leaving five primary psychological and behavioral assessments – anxiety, depression, sleep quality, post-traumatic stress, and alcohol use. We also remove the pulse monitoring and HRV biofeedback components as the Bluetooth 2 technologies were no longer compatible with current smartphones and tablets (e.g., Bluetooth 4). Furthermore we could not identify any commercially-available HR monitoring device that would provide quality HRV measurement.

The user interface was reworked to reflect a more contemporary look and feel for iOS and Android apps. This was done not only for aesthetic purposes but to ensure that prospective users would find the app familiar and easy to use. Legal information and acknowledgement of sources and contributors were added, along with engaging feature such as relaxing music and sounds to support sleep and enhance meditation practice. Finally the stress relaxation exercises were restructured into a course format, with both didactic and skills acquisition components, reflecting mindfulness stress relaxation courses like those given by universities and practitioners.

Sample screens of the PHIT for Duty app are presented below, beginning with the opening series (**Exhibit 10**). The refactored PHIT for Duty app will be made available to the general public for both iOS and Android devices, via both the Apple App store and the Google Play store.

Exhibit 10. Opening screen series presented each time the app is used.

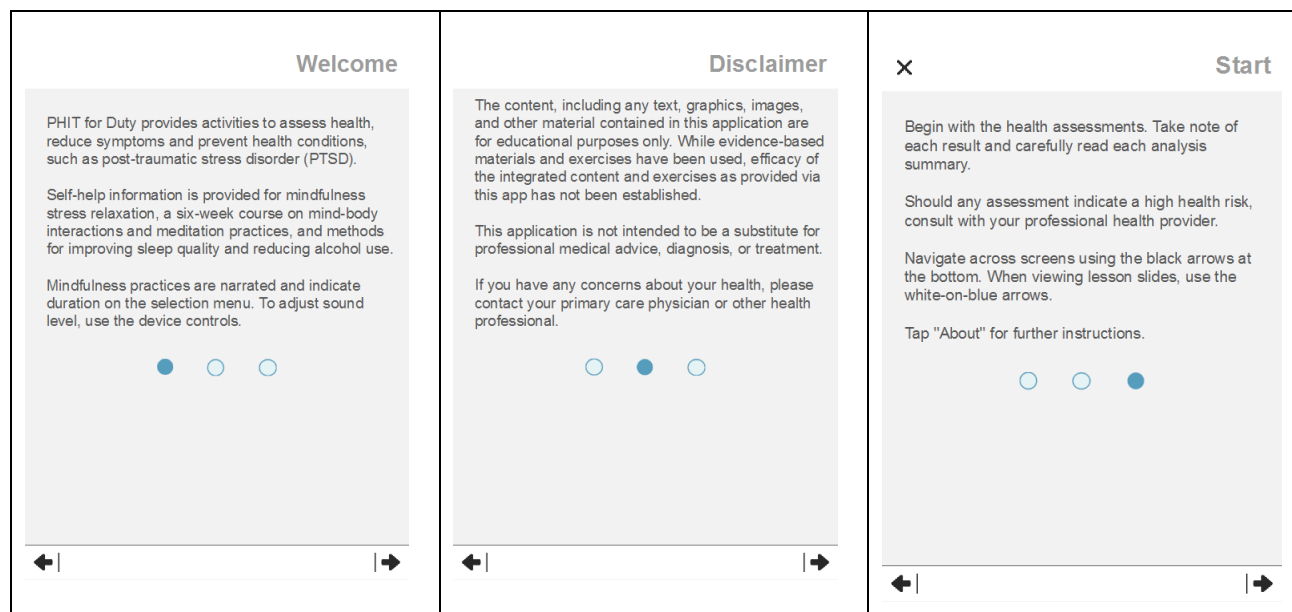


Exhibit 11. Initial menu, mindfulness introductions, and main menu while taking the course.

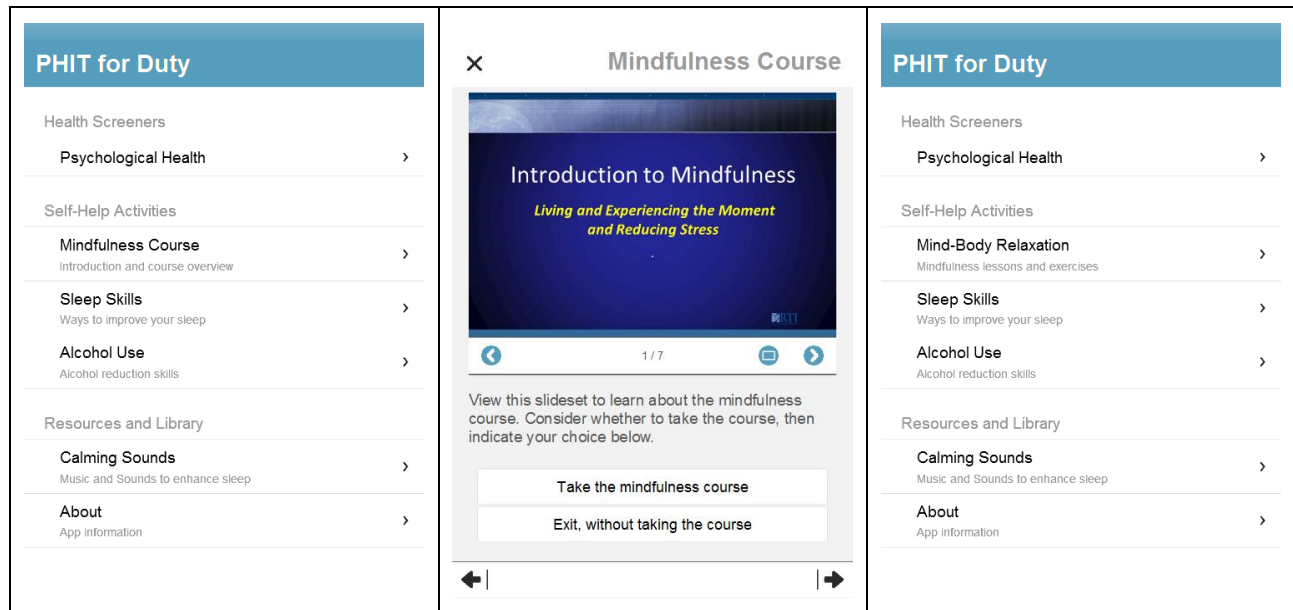


Exhibit 12. Example mindfulness course module showing module menu, didactic knowledge acquisition slides, and mindful meditation practice (with visuals).

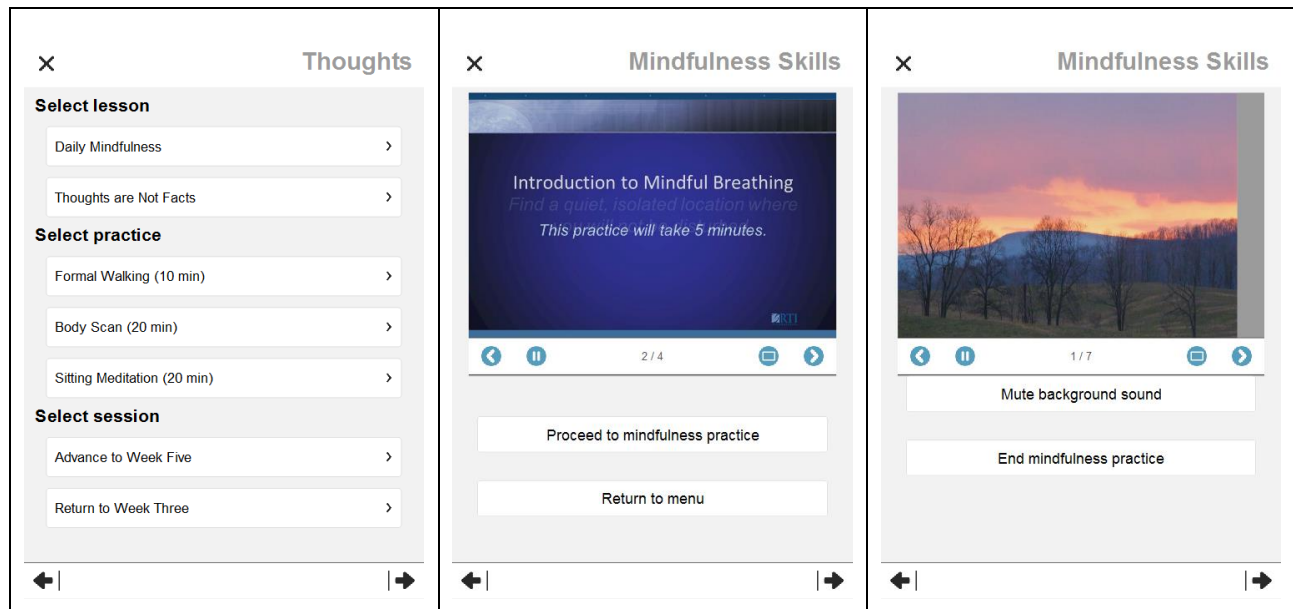


Exhibit 13. Menus to access all modules of the mind-body stress relaxation course.

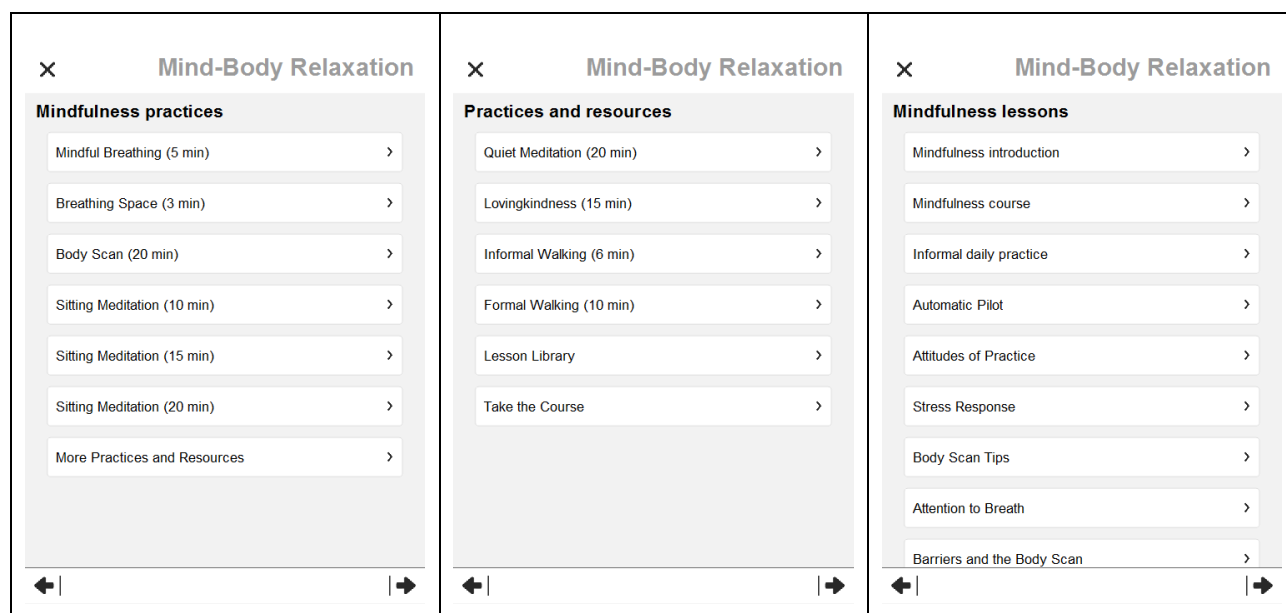


Exhibit 14. Example screens from the psychological assessment modules including assessments menu, a typical question, and feedback providing score and commentary.

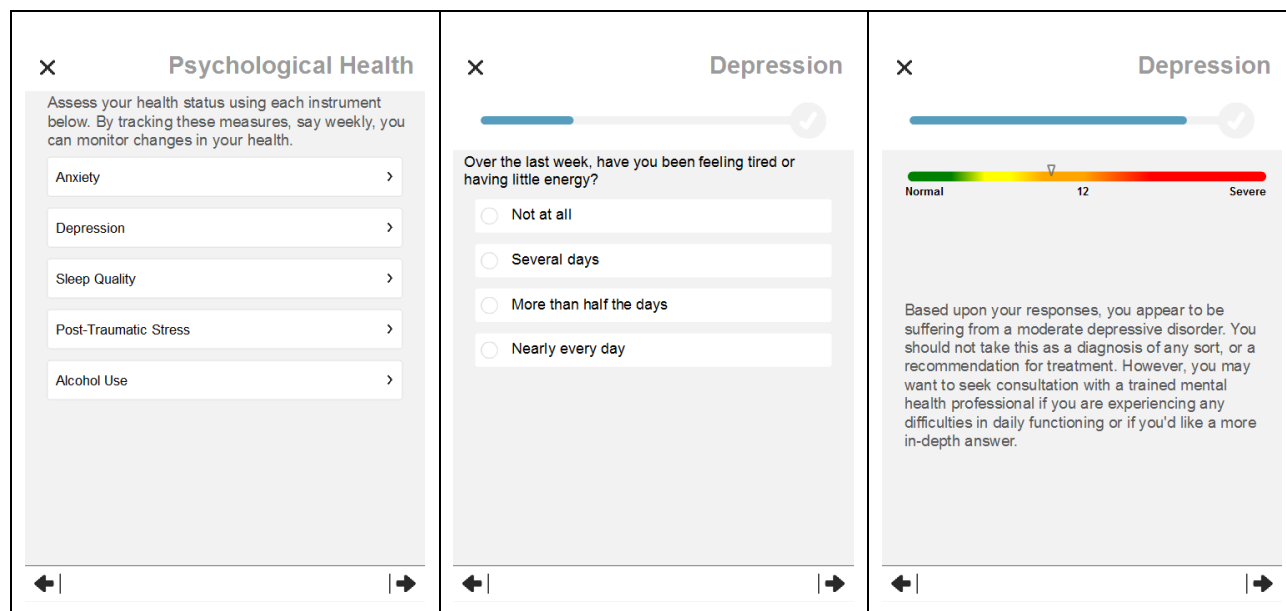


Exhibit 15. Seven health education modules provide information on improving sleep.

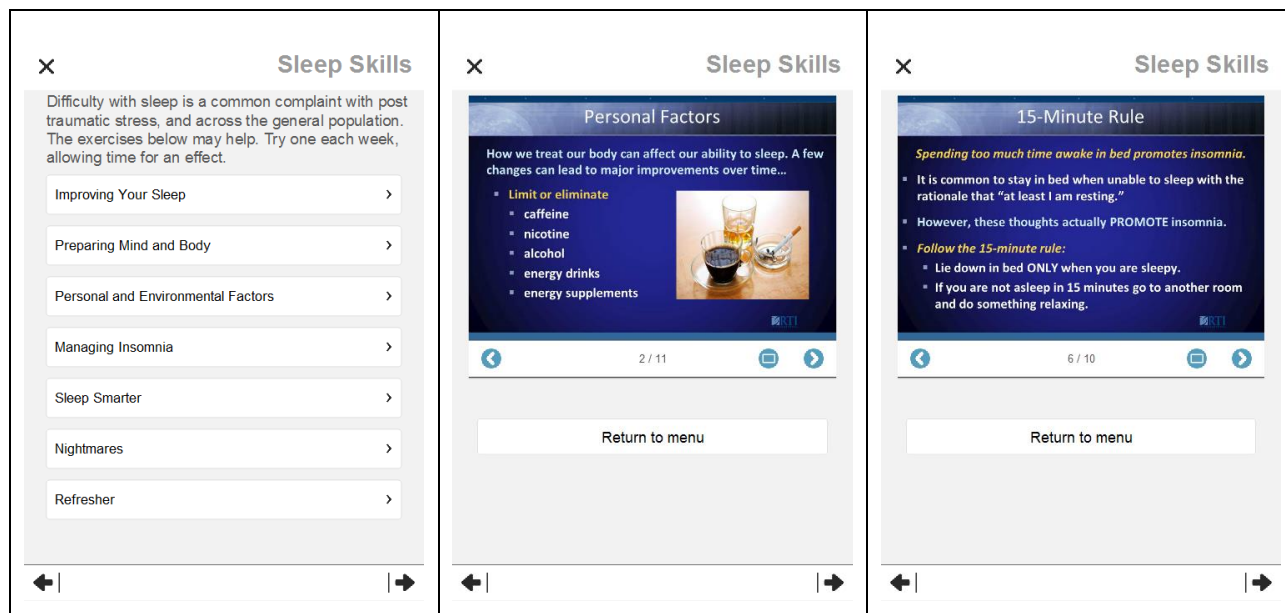


Exhibit 16. Five health education modules provide information on alcohol use, recognizing binge drinking, and suggesting methods to reduce alcohol use.

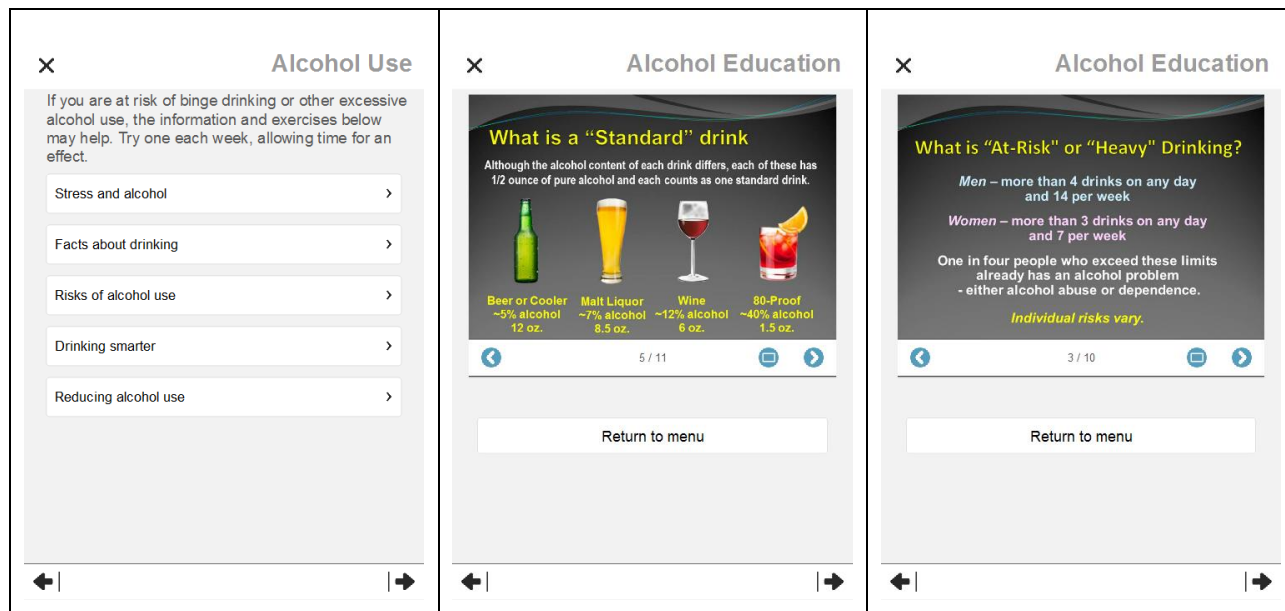
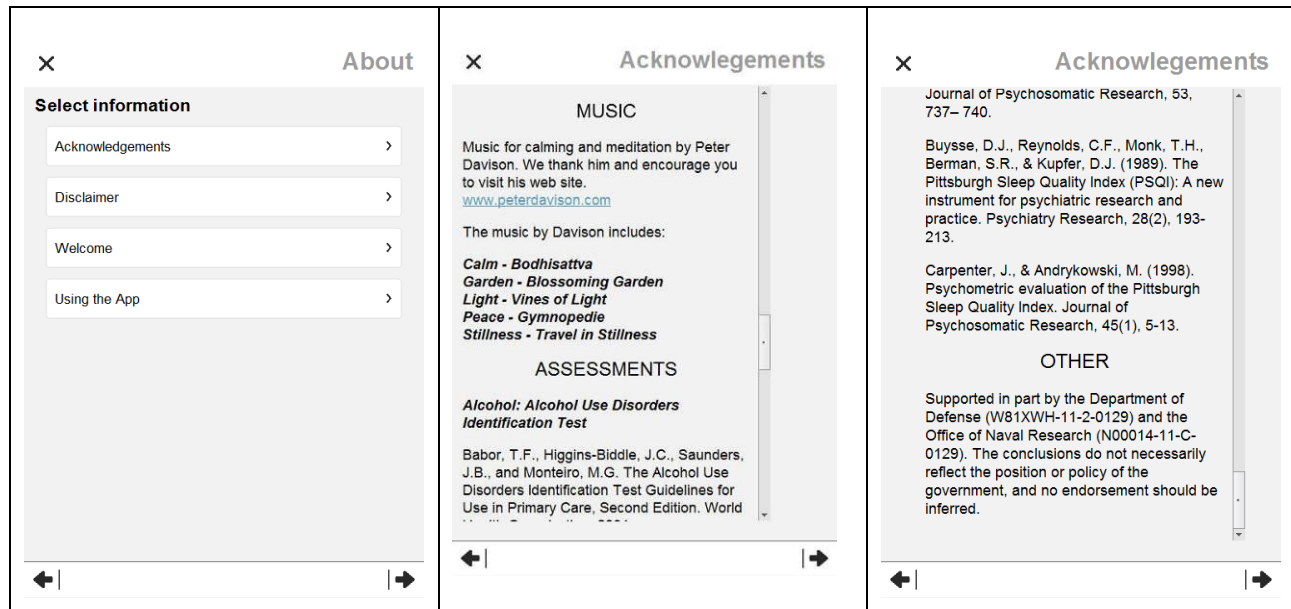


Exhibit 17. Acknowledgement of source materials, collaborators, and support is provided via the About menu along with access instructional and other information.



4. KEY RESEARCH ACCOMPLISHMENTS

- The PHIT for Duty app integrates self-report screening for stress, anxiety, sleep quality, depression, and alcohol use with mindfulness meditation, health education, and cognitive behavior change modules for reducing stress, attentional restructuring, improving sleep and reducing alcohol use.
- The Personal Health Intervention Toolkit facilitates designing instruments, user displays, task scheduling and data storage, so researchers can create a mobile application in much shorter time than development from scratch. Researchers can focus on the protocol, instruments, and interventions without having to worry about how the application is constructed, thereby implementing and evaluating mobile health interventions in less time and lower effort.
- A library of self-report assessments for psychological health, social health, and combat and environmental exposures are available for use by other researchers adopting the PHIT technologies.
- A library of self-help intervention modules for stress reduction, improving sleep, and reducing alcohol use has been developed and is readily available for reuse in other projects.
- The PHIT for Duty app will be made available to the general public for both iOS and Android devices, via both the Apple App store and the Google Play store.

5. REPORTABLE OUTCOMES

5.1. Manuscripts, abstracts, presentations

The following publications and presentations were made based on projects using either the PHIT framework or the PHIT for Duty mobile application:

Eckhoff, R. P., Kizakevich, P. N., Bakalov, V. D., Zhang, Y., Bryant, S. P., & Hobbs, M. A. (2015). A Platform to Build Mobile Health Apps: *The Personal Health Intervention Toolkit (PHIT)*. JMIR mHealth and uHealth, 3(2), e46. doi:10.2196/mhealth.4202.

Kizakevich, P. N., Eckhoff, R. P., Weger, S. A., Brown, J. M., Miller, S., Weeks, A. L., Bryant, S. P., Weimer, B. J., Bakalov, V. D., Zhang, Y., Spira, J. L. (2014, October). *PHIT for Duty – A Mobile Application to Improve Psychological Health and Reduce Alcohol Use in Persons with Post-Traumatic Stress*. Presented at Medicine 2.0: Social Media, Mobile Apps, and Internet/Web 2.0 in Health, Medicine and Biomedical Research, Malaga, Spain.

Eckhoff, R. P., Kizakevich, P. N., Bakalov, V. D., Zhang, Y., Bryant, S. P., & Hobbs, M. A. (2014, November). *PHIT™ – A Personal Health Intervention Toolkit for Building Mobile Health Applications*. Presented at Medicine 2.0'14 Summit & World Congress, Maui, HI.

Kizakevich, P. N., Eckhoff, R. P., Weger, S. A., Weeks, A. L., Brown, J. M., Bryant, S. P., Bakalov, V. D., Zhang, Y., Lyden, J. T., & Spira, J. L. (2014). *A personal health information toolkit for health intervention research*. Studies in Health Technology and Informatics, 199, 35–39.

Kizakevich, P. N., Eckhoff, R. P., Zhang, Y., Bryant, S. P., Bakalov, V. D., Weger, S. A., Lyden, J. T., & Weeks, A. L. (2014, April). *PHIT for Duty™, a Mobile Health Assessment and Intervention Application for Post Traumatic Stress and Psychological Disorders*. Poster presented at mHealth@Duke, Durham, NC. Best Poster Award.

Kizakevich, P. N., Eckhoff, R. P., Bakalov, V. D., Zhang, Y., Bryant, S. P., Lyden, J. T., Weger, S. A., Weeks, A. L., & Brown, J. M. (2013, October). *PHIT for Duty, a Mobile Health Assessment and Intervention Application for Post-Traumatic Stress and Psychological Disorders*. Poster presented at Inaugural Symposium on Using New Technologies to Enhance Healthy Behaviors, Chapel Hill, NC.

Kizakevich, P. N. (Invited Speaker). (2013, November). *Implementing PHIT, a mHealth Toolkit for Posttraumatic Stress and Health Intervention Research*. Presented at DoD/VA mHealth Summit, Arlington, VA.

Weger, S. A., Kizakevich, P., Eckhoff, R. P., Zhang, Y., Lyden, J. T., Bakalov, V. D., & Bryant, S. P. (2013, May). *PHIT for Duty: Exploring a mobile data collection framework*. Presented at AAPOR Annual Conference, Boston, MA.

Bagwell, J. E., Furberg, R. D., Kizakevich, P. N., Eckhoff, R. P., Zhang, Y., Bakalov, V. D., Simoni, D. A., Hobbs, C. L., & LaBresh, K. A. (2013, April). *A mobile clinical decision support tool for implementing the NHLBI Expert Panel Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents*. Poster presented at mHealth@Duke 2013, Durham, NC.

Kizakevich, P. N., Eckhoff, R. P., Lyden, J., Hubal, R., and Brown, J.. (2013, February). *PHIT for Duty™, a Mobile Health Assessment and Intervention Application for Post Traumatic Stress and Psychological Disorders*. Poster presented at Digital Health Communication Extravaganza, February 21, 2013, Orlando, FL.

Kizakevich, P. N., Hubal, R. C., Brown, J. M., Lyden, J. T., Spira, J. L., Eckhoff, R. P., Zhang, Y., Bryant, S. P., & Munoz, G. (2012). PHIT for Duty, a Mobile Approach for Psychological Health Intervention . *Studies in Health Technology and Informatics*, 181, 268–272. doi:10.3233/978-1-61499-121-2-268.

Zhang, Y., Roe, D. J., Keating, M. D., Kizakevich, P. N., Eckhoff, R. P., Bryant, S. P., Munoz, G., & Hubal, R. C. (2012, May). *SurveyPulse - A Cross-Platform Mobile Survey App Created with Adobe Flex*. Presented at IFDTC, Orlando, FL.

Kizakevich, P.N. (2012, January). Mobile technologies for health monitoring and intervention. Invited presentation, Raleigh Engineers Club, Raleigh, NC.

Eckhoff, R.P., Kizakevich, P.N., Zhang, Y., & Hubal, R.C. (2012, February). Personal Health Intervention Tool: A mobile framework using Adobe Flash Builder. Poster presented at the Digital Health Communication Extravaganza, Orlando, FL.

5.2. Licenses applied for and/or issued

- No patents or disclosures have been filed.
- RTI is working on releasing the PHIT framework to the open source community.
- The PHIT for Duty app will be made available free of charge to the general public for both iOS and Android devices, via both the Apple App store and the Google Play store.

5.3. Degrees obtained that are supported by this award

- None

5.4. Development of cell lines, tissue or serum repositories

- Not applicable

5.5. Infomatics such as databases and animal models

- None

5.6. Funding applied for based on work supported by this award

The PHIT mobile technology framework has been instrumental in the expansion of mobile application and intervention research across a variety of health domains with support from multiple funding agencies. The research projects listed below have made use of either the PHIT framework, and several have adapted or used health assessments or self-help interventions elements from the PHIT for Duty mobile app.

Completed and ongoing funded projects:

- **Pediatric CVD Risk Reduction.** A mobile clinical decision support tool for implementing the NHLBI Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescent. National Heart, Lung, and Blood Institute, Dr. Ken LaBresh, PI. Available on Apple mobile application store.
- **Flight Attendant Wellness.** PHIT-based substance abuse reduction in flight attendants. Substance and Mental Health Services Administration. Available on Apple and Google mobile application stores.
- **ActiSleep.** PHIT-based sleep diary for data collection in an adolescent sleep and marijuana study. National Institute on Drug Abuse, Dr. D. Fishbein (PI).
- **Adaption of Mindfulness Training to Treat Chronic Pain in the Military** National Center for Complementary and Alternative Medicine, Dr. S. Miller (PI).
- **Mocha.** PHIT-based monitoring outcomes for change in fragile X syndrome children. RTI Internal Research and Development award. Robert Furberg and Anne Wheeler (PIs).
- **Young Women's Co-op: Seek, Test, Treat and Retain For Youth and Young Adults Living with or at High Risk for Acquiring HIV.** Comparison of conventional and mobile app-based HIV prevention models for poor, young, at-risk African American women who use substances and are sexually active. National Institute on Drug Abuse, Dr. Wendee Wechsberg (PI).
- **Development of an App for Preconception Health.** CDC Foundation, Linda Squires (PI).
- **Accessing CVD Risk Factors among Minority College Students.** PHIT-based health interventions for improving cardiovascular wellness. National Institutes of Health. Vanessa Duren-Winfield, PhD, (PI). Winston-Salem State University
- **PHIT-App Development Services.** Multiple mobile research apps are in development which are based on the PHT framework and the PHIT for Duty program, including the following topics: (1) adolescent asthma self-management, (2) mobile heart rate variability assessment, and (3) post-partum depression. Supported via the North Carolina Translational and Clinical Sciences Institute (NC TraCS). Funded by a Clinical and Translational Science Award from the National Center for Advancing Translational Sciences, National Institutes of Health, grant UL1TR001111

Pending award or in-review:

- **Evaluation of HRV as a Resilience Building Intervention in the Reserve Component** (Pending). PHIT-based HRV biofeedback-assisted resilience training (HRV-BART) protocol for impact on resilience. CDMRP, Dr. Laurel Hourani (PI)

-
- **Using Innovative Smartphone Design to Assess the Nature and Consequences of the Zika Virus for Low-Income Families in Brazil** (in review).
National Institutes of Health, Dr. Anne Wheeler (PI).

6. CONCLUSIONS

- The Personal Health Intervention Toolkit facilitates designing instruments, user displays, task scheduling and data storage, so researchers can create a mobile application in much shorter time than development from scratch. Researchers can focus on the protocol, instruments, and interventions without having to worry about how the application is constructed, thereby implementing and evaluating mobile health interventions in less time and lower effort.
- Usability evaluation of the PHIT for Duty health assessments, physiological sensors, system acceptability, and overall system functionality have shown positive results and affirmation of the PHIT mobile application framework design.
- Multiple research projects have benefitted from the PHIT framework development, including mindfulness training for chronic pain in wounded warriors

7. REFERENCES

Kizakevich, P. N., Hubal, R. C., Brown, J. M., Lyden, J. T., Spira, J. L., Eckhoff, R. P., Zhang, Y., Bryant, S. P., & Munoz, G. (2012). PHIT for Duty, a Mobile Approach for Psychological Health Intervention . *Studies in Health Technology and Informatics*, 181, 268–272. doi:10.3233/978-1-61499-121-2-268

Kizakevich, P. N., Eckhoff, R. P., Weger, S. A., Weeks, A. L., Brown, J. M., Bryant, S. P., Bakalov, V. D., Zhang, Y., Lyden, J. T., & Spira, J. L. (2014). *A personal health information toolkit for health intervention research*. *Studies in Health Technology and Informatics*, 199, 35–39.

Eckhoff, R. P., Kizakevich, P. N., Bakalov, V. D., Zhang, Y., Bryant, S. P., & Hobbs, M. A. (2015). A Platform to Build Mobile Health Apps: *The Personal Health Intervention Toolkit (PHIT)*. *JMIR mHealth and uHealth*, 3(2), e46. doi:10.2196/mhealth.4202